208.1009

UNITED STATES PATENT & TRADEMARK OFFICE

Re: Application of: LESLIE, Stewart Thomas

Serial No.: To Be Assigned

Filed: Simultaneously Herewith

For: **TRANSDERMAL DOSAGE FORM**

PRELIMINARY AMENDMENT

October 25, 2001

Assistant Commissioner for Patents
Washington, D.C. 20231
BOX: PATENT APPLICATION

Sir:

Please amend the above-identified application as follows:

IN THE CLAIMS.

Please **amend** the claims as follows:

"Express Mail" mailing label no. EL 914492619US.
Date of deposit: October 25, 2001.
I hereby certify that this correspondence and/or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the indicated date above in an envelope addressed to: "Assistant Commissioner for Patents, Washington, D.C. 20231".
DAVIDSON, DAVIDSON & KAPPEL, LLC
BY: Samuel Borodach

3. (Amended) A composition according to claim 1, wherein the distressing substance is selected from the group consisting of emetics, nauseants and flavouring or bitter substances.

4. (Amended) A composition according to claim 3, wherein the distressing substance is selected from the group consisting of ergolides; quatenary ammonium compounds; non-permeant opioid antagonists; other opioid antagonists; emetics; and atropine or salts thereof.

5. (Amended) A composition according to claim 1, wherein the distressing substance is non-permeant and is incorporated in a vehicle being the same vehicle as for the opioid analgesic.

7. (Amended) A composition according to claim 1, wherein the opioid analgesic is selected from the group consisting of morphine, hydromorphone, buprenorphine, ketamine, fentanyl, tramadol, or pharmaceutically acceptable and percutaneously transmissible salts thereof.

8. (Amended) A composition according to claim 1 wherein the opioid analgesic is a narcotic opioid analgesic.

9. (Amended) A composition according to claim 1, wherein the opioid analgesic is in an aqueous and/or alcoholic solution, or incorporated in a matrix including a pressure sensitive adhesive.

10. (Amended) A transdermal device containing a composition according to claim 1.

13. (Amended) A device according to claim 10, which is a monolithic patch.

14. (Amended) A composition according to claim 1, which contains buprenorphine or pharmaceutically acceptable salt thereof as the opioid analgesic and atropine or pharmaceutically

acceptable salt thereof, or an ergolide or pharmaceutically acceptable salt thereof as the distressing substance.

Please **add** the following new claim:

15. (New) A device according to claim 10, which contains buprenorphine or pharmaceutically acceptable salt thereof as the opioid analgesic and atropine or pharmaceutically acceptable salt thereof, or an ergolide or pharmaceutically acceptable salt thereof as the distressing substance.

REMARKS

Claims 3-5, 7-10 and 13-14 have been amended herewith to remove multiple dependencies in order to reduce filing fees. Claim 15 has been added. Support for new claim 15 can be found throughout the specification as originally filed, e.g., original claim 14. No new matter has been added by virtue of this amendment.

Applicants believe that the claims are in condition for allowance. An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claim 15 has been added.

Claims 3-5, 7-10 and 13-14 have been amended as follows:

3. (Amended) A composition according to claim 1[or 2] , wherein the distressing substance is selected from the group consisting of [chosen from] emetics, nauseants and flavouring or bitter substances.

4. (Amended) A composition according to claim 3, wherein the distressing substance is selected from the group consisting of [chosen from] ergolides; quatenary ammonium compounds; non-permeant opioid antagonists; other opioid antagonists; emetics; and atropine or salts thereof.

5. (Amended) A composition according to claim 1 [any preceding claim], wherein the distressing substance is non-permeant and is incorporated in a vehicle being the same vehicle as for the opioid analgesic.

7. (Amended) A composition according to claim 1 [any preceding claim], wherein the opioid analgesic is selected from the group consisting of [chosen from] morphine, hydromorphone, buprenorphine, ketamine, fentanyl, tramadol, or pharmaceutically acceptable and percutaneously transmissible salts thereof.

8. (Amended) A composition according to claim 1 [any preceding claim] wherein the opioid analgesic is a narcotic opioid analgesic.

9. (Amended) A composition according to claim 1 [any preceding claim], wherein the opioid analgesic is in an aqueous and/or alcoholic solution, or incorporated in a matrix including a pressure sensitive adhesive.

10. (Amended) A transdermal device containing a composition according to claim 1 [any preceding claim].

13. (Amended) A device according to claim 10, which is a monolithic patch.

14. (Amended) A composition according to claim 1 [any of claims 1 to 9, or a device according to any of claims 10 to 13], which contains buprenorphine or pharmaceutically acceptable salt thereof as the opioid analgesic and atropine or pharmaceutically acceptable salt thereof, or an ergolide or pharmaceutically acceptable salt thereof as the distressing substance.